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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/393,743	09/10/99	DUPONCHELLE	A DI-5417

HM12/0801

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EXAMINER

CHOI, F

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 08/01/00

4

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

<p align="center"><b>Office Action Summary</b></p>	<p>Application No.</p> <p>09/393,743</p>	<p>Applicant(s)</p> <p>DUPONCHELLE ET AL.</p>	
	<p>Examiner</p> <p>Frank I Choi</p>	<p>Art Unit</p> <p>1616</p>	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 7-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) \_\_\_\_.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

**Attachment(s)**

- |   |  |
|---|--|
| 15) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                  | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____   |
| 16) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)              | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>3</u> . | 20) <input type="checkbox"/> Other:  |

**DETAILED ACTION**

***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-6, drawn to a two-part bicarbonate containing solution, classified in class 424, subclass 717.
- II. Claims 7-11, drawn to a multi-chamber container, classified in class 383, subclass 38.
- III. Claims 12-20, drawn to a method of stabilizing bicarbonate solutions, classified in class 53, subclass 425.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, invention II has separate utility such as a multi-compartment bag. See MPEP § 806.05(d).

Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product such as storing other fluids (See Balteau et al. (US Pat. 5,431,496)).

Alternatively, Inventions III and I, II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as

claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the process as claimed can be used to make other and materially different product, for instance, shelf stable pre-mixes that are combinable to form ready-to-cook mixes or food beverage products (See Bunke et al).

Alternatively, Inventions III and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the apparatus as claimed can be used to practice another and materially different process (See Bunke et al.)

Alternatively, Inventions II and I are related as apparatus and product made. The inventions in this relationship are distinct if either or both of the following can be shown: (1) that the apparatus as claimed is not an obvious apparatus for making the product and the apparatus can be used for making a different product or (2) that the product as claimed can be made by another and materially different apparatus (MPEP § 806.05(g)). In this case, the product as claimed can be made by another and materially different apparatus, for instances, having two completely separate containers with tubing leading from each to a common tube wherein the streams from the separate tubes combine to form the product.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and the search for each Group is not required for the other, in that Group I requires the search of specific amounts of the

constituents in combination which Groups II, III do not, and Group III requires the search of sterilization and methods of preparing the product which Groups I, II do not, restriction for examination purposes as indicated is proper. In light of the above, prosecution of all claims would appear to constitute an undue burden on Examiner.

During a telephone conversation with Paula Kelly on 7/26/00 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-6. Affirmation of this election must be made by applicant in replying to this Office action. Claims 7-20 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Claim Rejections - 35 USC § 102103***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 5 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over EP 0 935 967.

EP 0 935 967 expressly discloses a two part bicarbonate containing solution comprising an first individual solution having pH of 2.8-3.2 and containing glucose, and a second individual solution comprising bicarbonate having a pH of 8-8.5, which when mixed with each other have a pH of 7.2-7.4, wherein each solution is stored separately in a double-chamber bag (Columns 5, 6, Claims 1-11).

Alternatively, at the very least the claimed invention is rendered obvious within the meaning of 35 USC 103, because the prior art discloses products and uses that contain the same exact ingredients/components as that of the claimed invention. See *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980). See also *In re May*, 197 USPQ 601, 607 (CCPA 1978).

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 935 967 in view of Alexander et al.

EP 0 935 967 teaches a two part bicarbonate containing solution comprising an first individual solution having pH of 2.8-3.2 and containing glucose, and a second individual solution comprising bicarbonate having a pH of 8-8.5, which when mixed with each other have a pH of 7.2-7.4, wherein each solution is stored separately in a double-chamber bag (Columns 5, 6, Claims 1-11). It is taught that a peritoneal dialysis solutions consists of three functional components: electrolytes such as calcium, sodium and magnesium in the form of chlorides, a buffer system such as bicarbonate in acid with carbon dioxide, lactate or similar substances, an osmotic agent such as glucose (Column 1, lines 6-25). It is taught that by keeping the

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bicarbonate content less than 10 mmol/L the handling problems associated with customary bicarbonate containing solutions and the necessity of a carbon dioxide barrier film can be circumvented (Column 2, lines 46-58).

Alexander et al. teach that glucose, glucose polymer, amino acids, protein hydrolyzates are added to dialysis solutions to enhance ultrafiltration and serve the dual purpose of providing nutrition to the dialysis patient (Column 3, lines 12-68, Column 4, lines 1-24). It is taught that it is known in the art to prepare glucose polymers by hydrolysis of starch (Column 3, lines 31-38).

The difference between the prior art and the claimed invention is that the cited invention does not expressly disclose that the multi-chamber bag is composed of gas-permeable material or the specific ranges of amounts of the components of the bicarbonate solution. However the prior art amply suggests the same as it is notoriously well known in the art to vary the amount of electrolytes, osmotic agents, and buffers according to the needs of the dialysis patient, as such, it would have been well within the skill of one of ordinary skill in the art to have arrived at various amounts of said components, including amounts within the claimed ranges, by optimization of the prior art values. Further, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to utilize a multi-chamber bag having a gas permeable material as the concentration of bicarbonate permits the use of commonly used container materials without having modify the same with a carbon dioxide barrier and employ the above osmotic agents with the expectation that the same would improve ultrafiltration.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the prior art.

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over duMoulin et al. and Alexander et al.

duMoulin et al. teach a two part bicarbonate containing solution comprising a first part having a pH of 4.5 to 5.8 and a second part comprising bicarbonate having a pH of 7.2 to 10 which when mixed have a pH of 7.2 to 7.6, which are contained in separate chambers of a bag with two chambers (Column 7, lines 12, 13, 35-55). It is taught that the first part contains acids such as lactate and acetate and an osmotically active substance such as glucose, polyglucose or glycerol (Column 7, lines 22-30). It is taught that the second part contains amino acids or peptides and that the amino acids or peptides allow the pH of solutions to be very easily and accurate adjusted (Column 2, lines 9-15, 30-39). It is taught that the concentration of the carboxylic acids is preferably 10 to 60 mmoles/L, that the concentrations of sodium, chlorine, calcium, magnesium and potassium are well known in the art, and that the concentration of bicarbonate is from 23-26 mmoles/L (Column 2, lines 51-55, 63-68).

Alexander et al. teach that glucose, glucose polymer, amino acids, protein hydrolyzates are added to dialysis solutions to enhance ultrafiltration and serve the dual purpose of providing nutrition to the dialysis patient (Column 3, lines 12-68, Column 4, lines 1-24). It is taught that it is known in the art to prepare glucose polymers by hydrolysis of starch (Column 3, lines 31-38).

The difference between the prior art and the claimed invention is that the cited invention does not expressly disclose the specific ranges of amounts of the components of the bicarbonate solution or the pH's of the individual solutions. However the prior art amply suggests the same as it is notoriously well known in the art to vary the amount of electrolytes, osmotic agents, and buffers according to the needs of the dialysis patient, as such, it would have been well within the



skill of one of ordinary skill in the art to have arrived at various amounts of said components, including amounts within the claimed ranges, by optimization of the prior art values. Further, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art as above so as to prepare a dialysis solution which meets the unique needs of each dialysis patient and utilize the various osmotic agents as they would have been expected to also provide nutritional benefits to the dialysis patient.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the prior art.

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Veltman in view of Alexander et al., Ing et al., Balteau et al. and Segers et al.

Veltman teaches a two-part dialysis solution comprising an acid concentrate containing acetate or lactate ion and calcium chloride and magnesium chloride and a bicarbonate concentrate containing sodium bicarbonate, sodium chloride, and potassium chloride and that the final pH is between 7.2 and 7.4 (Column 3, lines 35-51, Columns 4-9).

Alexander et al. teach that glucose, glucose polymer, amino acids, protein hydrolyzates are added to dialysis solutions to enhance ultrafiltration and serve the dual purpose of providing nutrition to the dialysis patient (Column 3, lines 12-68, Column 4, lines 1-24). It is taught that it is known in the art to prepare glucose polymers by hydrolysis of starch (Column 3, lines 31-38).

Balteau et al. teach an improved multiple chamber container for housing and dispensing a plurality of products including peritoneal dialysis solutions which allows the filling and mixing

of two or more products prior to administration of the mixed products to a patient and without product degradation (Column 2, Column 3, lines 1-3).

Ing et al. teach that the single-container method of administering dialysis solutions wherein a bicarbonate solution and acid solution are contained in separate compartments of a two-compartment bag is well known in the art (Pg. 122).

Segers et al. teach a method of manufacturing and storing stable bicarbonate solutions by storing a two-part bicarbonate solution in a multi-compartment bag which is gas permeable to allow carbon dioxide which generated in another compartment to enter the bicarbonate compartment which stabilizes the bicarbonate and that for purposes of convenience the chambers of the bag can be composed of the same gas permeable material (Column 3, lines 33-54, Column 7, lines 13-65).

The difference between the prior art and the claimed invention is that the cited invention does not expressly disclose the use of a multi-chamber bag which is composed of gas-permeable material or the specific ranges of amounts of the components and pH's of the bicarbonate solution. However the prior art amply suggests the same as it is notoriously well known in the art to vary the amount of electrolytes, osmotic agents, and buffers according to the needs of the dialysis patient, and to prepare two-part dialysis solutions, one being a basic solution, and the other an acidic solution, as such, it would have been well within the skill of one of ordinary skill in the art to have arrived at various amounts of said components and pH's, including amounts within the claimed ranges, by optimization of the prior art values. Also, the use of multi-chambered bags and osmotic agents are well known in the art. Further, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to utilize a

multi-chamber bag having a gas permeable material so as to allow entry of carbon dioxide which generated in another chamber to stabilize the bicarbonate in the one of the chambers and to avoid the inconvenience of having to manufacture a multi-compartment bag wherein the compartments are made of different materials, as the concentration of bicarbonate permits the use of commonly used container materials without having modify the same with a carbon dioxide barrier and employ the above osmotic agents with the expectation that the same would improve ultrafiltration.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

#### ***Conclusion***

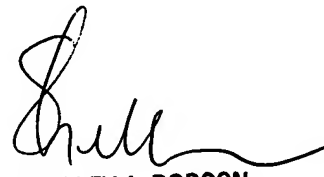
A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machines are (703) 308-4556 or (703) 305-3592.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (703) 308-0067.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. José Dees, can be reached on (703) 308-4628.

FIC

July 28, 2000

  
SHELLEY A. DODSON  
PRIMARY EXAMINER

